009042

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 15 1992

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT **DIMETHYLAMINE SALT OF 2,4-D ACID:** Acute Toxicity Studies.

FROM: Jess Rowland, M.S, Toxicologist 01/07/92
Section II, Toxicology Branch II
Health Effects Division (H7509C)

TO: W.Waldrop/J.Coombs
Product Manager (71)
Reregistration Division

THRU: K.Clark Swentzel, Section Head 1/10/92
Section II, Toxicology Branch II
Health Effects Division (H7509C)
and
Marcia van Gemert, Ph.D., Chief 1/14/92
Toxicology Branch II
Health Effects Division (H7509C)

PROJECT/STUDY IDENTIFICATIONS: Submission: S401000

HED Project No. 1-2003 Caswell No. 315 O

TRID No(s): 470165-038; 470165-039; 470165-040; 470165-041; 470165-042 470165-043

Registrant: Dow Chemical Co.

ACTION REQUESTED: Review acute toxicity studies for 2,4-D DMA submitted before issuance of Registration Standard for 2,4-D (no record of prior review).

RESPONSE: The acute toxicity [oral, dermal, inhalation, eye and skin irritation, and dermal sensitization] studies of DMA 6 Weed Killer, a herbicide formulation containing dimethylamine salts of 2,4-dichlorophenoxyacetic acid, are classified as **CORE GUIDELINE and satisfies the Guideline requirements 81-1, 81-2, 81-3, 81-4, 81-5, and 81-6.** A seperate Data Evaluation Report for each of study is attached.

PRIMARY REVIEWER: Jess Rowland, M.S, Toxicologist 01/06/92
Section II, Tox.Branch II

SECONDARY REVIEWER: K. Clark Swentzel, Section Head
Section II, Tox. Branch II 1/10/92

DATA EVALUATION REPORT

STUDY TYPE: Acute Oral Toxicity **GUIDELINE:** 81-1

Caswell No. 315 O TRID No. 470165-038 HED PROJECT No. 1-2003

TEST MATERIAL: Dimethylamine salt of 2,4-Dichlorophenoxyacetic acid

SYNONYM: DMA 6 Weed Killer

REGISTRANT: Dow Chemical Co. Midland, MI

TESTING LABORATORY: Mammalian and Environmental Toxicology Research Laboratory, Dow Chemical Co.

STUDY IDENTIFICATION: None

TITLE OF REPORT: DMA 6 Weed Killer: Acute Oral Toxicity Study in Fischer 344 Rats

AUTHORS: M.M. Jeffrey, J.E. Battjes, D.L. Eisenbrandt and K.S. Rao

REPORT DATE: February 17, 1986

CONCLUSION: The acute oral toxicity of DMA 6 Weed Killer, a herbicide formulation containing dimethylamine salts of 2,4-dichlorophenoxyacetic acid (57.9%), was evaluated in male and female Fischer 344 rats. The oral LD_{50} values were >1000 mg/kg for males and approximately 1000 mg/kg for females.

TOXICITY CATEGORY: III

CORE CLASSIFICATION: **Guideline**; satisfies Guideline requirement [81-1] for an acute oral toxicity study.

I. INTRODUCTION

This Data Evaluation Report (DER) summarizes the experimental procedures and results of an acute oral toxicity study of DMA 6 Weed Killer in rats.

II. MATERIALS AND METHODS

1. Test Material

Common Name:	DMA 6 Weed Killer
Active Ingredient:	**DMA salt of 2,4-D Acid**
Composition:	57.9% 2,4-D acid equivalent
Batch/Lot No.	GHD-0832-46.
Description:	Brown liquid
Flash Point:	TCC >195°F
pH	6.8-7.2

2. Test Animals

Species: Rats
Strain: Fischer 344
Sex: Males and Females
Age: 9 weeks
Identification: Ear tags.

3. Animal Husbandry

Housing: 3/cage.
Food: Purina Certified Rodent Chow #5002 ad libitum
Water: tap water ad libitum
Environment: Temperature- 21±2°C; Humidity- 40-60%

4. Treatment

Following an overnight fast, groups of 6 male and 6 female rats were given a single oral administration of undiluted DMA 6 Weed Killer at 250, 500 or 1000 mg/kg. Animals were observed for clinical signs of toxicity daily and body weights were obtained prior to treatment, on the day of treatment and weekly thereafter during a two-week observation period. Following a 2-week observation period, all animals were sacrificed and a complete necropsy was performed.

5. Quality Assurance

A quality assurance statement was included in the report.

III. RESULTS

1. Mortality

Dose (mg/kg)	Male	Female
250	0/6	0/6
500	0/6	0/6
1000	0/6	4/6

2. Clinical Observations

Dose (mg/kg)	Clinical Signs	Males	Female
250	None observed	--	--
500	None observed	--	--
1000	Lethargy	6/6	6/6
	Palpebral closure	2/6	1/3
	Loss of motor coordination	0/6	6/6
	Excessive Lacrimation	0/6	2/6
	Rapid Shallow Respiration	0/6	2/6

3. Body Weight

Surviving rats gained weight throughout the study.

4. Necropsy

No treatment-related changes were observed in rats that died or in those sacrificed at termination. The nonspecific changes observed in the gastrointestinal tract of four females that died during the study were attributed to stress.

IV. CONCLUSION

The acute oral toxicity of DMA 6 Weed Killer was evaluated in male and female Fischer 344 rats. The LD_{50} values were >1000 mg/kg for males and approximately 1000 mg/kg for females.

TOXICITY CATEGORY: III

V. CORE CLASSIFICATION: Guideline; satisfies Guideline requirement [81-1] for an acute oral toxicity study.

PRIMARY REVIEWER: Jess Rowland, M.S, Toxicologist
Section II, Tox.Branch II

SECONDARY REVIEWER: K. Clark Swentzel, Section Head
Section II, Tox. Branch II

DATA EVALUATION REPORT

STUDY TYPE: Acute Dermal Toxicity **GUIDELINE:** 81-2

Caswell No. 315 O TRID No. 470165-039 HED PROJECT No. 1-2003

TEST MATERIAL: Dimethylamine salt of 2,4-Dichlorophenoxyacetic acid

SYNONYM: DMA 6 Weed Killer

REGISTRANT: Dow Chemical Co. Midland, MI

TESTING LABORATORY: Mammalian and Environmental Toxicology Research Laboratory, Dow Chemical Co.

STUDY IDENTIFICATION: None

TITLE OF REPORT: DMA 6: Acute Dermal Toxicity Study in New Zealand White Rabbits.

AUTHORS: R.E. Carreon, D.J. Schuetz, L.G. Lomax and K.S. Rao

REPORT DATE: February 21, 1986

CONCLUSION: The acute dermal toxicity of DMA 6, a herbicide formulation containing dimethylamine salts of 2.4-dichlorophenoxyacetic acid (57.9%), was evaluated in male and female New Zealand White Rabbits. The dermal LD_{50} values were 1122 mg/kg for males and 909 mg/kg for females.

TOXICITY CATEGORY: II

CORE CLASSIFICATION: Guideline; satisfies Guideline requirement [81-2] for an acute dermal toxicity study.

I. INTRODUCTION

This Data Evaluation Report (DER) summarizes the experimental procedures and results of an acute dermal toxicity study of DMA 6 in rabbits.

II. MATERIALS AND METHODS

1. Test Material

Common Name:	DMA 6 Weed Killer
Active Ingredient:	**DMA salt of 2,4-D Acid**
Composition:	57.9% 2,4-D acid equivalent
Batch/Lot No.	GHD-0832-46.
Description:	Brown liquid
Flash Point:	TCC >195°F

2. Test Animals

Species:	Rabbit
Strain:	New Zealand White
Sex:	Males and Females
Weight:	2.1 to 2.9 kg
Identification:	Ear tags.

3. Animal Husbandry

Housing:	1/cage.
Food:	Purina Certified Rabbit Chow #5322 ad libitum
Water:	Tap water ad libitum
Environment:	Temperature- 21±2°C; Humidity- 40-60%
Acclimation:	Two weeks

4. Treatment

Following the removal of hair from the dorsal and ventral area of the trunk 24 hour earlier, groups of 5 male and 5 female rabbit were treated with a single dermal application of undiluted test material at 200, 630 or 2000 mg/kg. The test material wa held in contact with the skin with a porous gauze dressing and non-irritating tape. A heavy-gauge plastic cuff was next placed over the trunk of the animal and secured with rubber bands. The plastic cuff was then covered by a cloth bandage, which was taped securely to the adjacent hair. Following a 24-hour exposure period, the cuffs were removed, observations were made for any reaction at the site of application. The skin was washed with mild soap and water, rinsed thoroughly and dried with a soft disposable towel. Rabbits were observed for clinical signs of toxicity daily and body weights were obtained prior to treatment, and at 1, 7, and 14 days post-treatment. Following a 2-week observation period, all animals were sacrificed and a complete necropsy was performed.

5. Quality Assurance

A quality assurance statement was included in the report.

III. RESULTS

1. Mortality

Dose (mg/kg)	Male	Female
200	0/5	0/5
630	0/5	1/5
2000	5/5	5/5

2. Dermal Observations

Dose (mg/kg)	Total No.	ERYTHEMA		EDEMA		
		Slight	Moderate	Slight	Moderate	Marked
200	10	1 F	--	--	--	--
630	10	3 M, 3 F	1 M, 2 F	2 M, 3 F	1 M, 1 F	1 F
2000	2	--	1 M	1 F	1 M	--

2. Clinical Observations

Dose (mg/kg)	Clinical Signs	Males	Female
200	Loss of appetite	0	2/5
630	Lethargy	0	2/5
	Loss of appetite	0	1/5
	Loss of motor coordination	0	1/5
2000	Lethargy	5/5	3/5
	Rapid respiration	1/5	0/5
	Labored respiration	1/5	1/5
	Spasms (myotonia-like)	4/5	3/5
	Semiconsciousness	1/5	0/5

3. Body Weight

Rabbits receiving 630 or 2000 mg/kg initially lost weight following treatment (Day 1); however, by the end of the two-week observation period, all surviving rabbits had steadily gained weight.

4. Necropsy

Except for the skin erythema/hyperemia observed at the dermal test site, no treatment-related gross pathological changes were seen.

IV. CONCLUSION

The acute dermal toxicity of DMA 6, a herbicide formulation containing dimethylamine salts of 2.4-dichlorophenoxyacetic acid (57.9%), was evaluated in male and female New Zealand White Rabbits. The dermal LD_{50} values were 1122 mg/kg for males and 909 mg/kg for females.

TOXICITY CATEGORY: II

V. CORE CLASSIFICATION: **Guideline;** satisfies Guideline requirement [81-2] for an acute dermal toxicity study.

PRIMARY REVIEWER: Jess Rowland, M.S, Toxicologist
Section II, Toxicology Branch II

SECONDARY REVIEWER: K. Clark Swentzel, Section Head
Section II, Toxicology Branch II

Jess Rowland 01/09/92

DATA EVALUATION REPORT

STUDY TYPE: Acute Inhalation Toxicity **GUIDELINE:** 81-3

Caswell No. 315 O **TRID No. 470165-040** **HED PROJECT No. 1-2003**

TEST MATERIAL: Dimethylamine salt of 2,4-Dichlorophenoxyacetic acid

SYNONYM: DMA 6 Weed Killer

REGISTRANT: Dow Chemical Co. Midland, MI

TESTING LABORATORY: Mammalian and Environmental Toxicology Research Laboratory, Dow Chemical Co.

STUDY IDENTIFICATION: None

TITLE OF REPORT: DMA-6 Sequestered Weed Killer: An Acute Aerosol Inhalation Study With Rats

AUTHORS: C.M. Streeter, J.E. Battjes, L.G. Lomax and T.D. Landry

REPORT DATE: None

CONCLUSION: The acute inhalation toxicity of DMA 6 Weed Killer, a herbicide formulation containing 68.1% of the dimethylamine salt of 2,4-dichlorophenoxyacetic acid, was evaluated in male and female Fischer 344 rats. The highest attainable time-weighted concentration (3.5 mg/L) produced no compound-related toxicity. The nominal concentration for the 3.5 mg/L exposure was 12 mg/L. The inhalation LD_{50} was > 3.5 mg/L.

TOXICITY CATEGORY: III

CORE CLASSIFICATION: **Guideline**; satisfies Guideline requirement [81-3] for an acute inhalation toxicity study.

I. INTRODUCTION

This Data Evaluation Report (DER) summarizes the experimental procedures and results of an acute inhalation toxicity study of DMA 6 Weed Killer in rats.

II. MATERIALS AND METHODS

1. Test Material

Common Name:	DMA 6 Weed Killer
Active Ingredient:	**DMA salt of 2,4-D Acid**
Composition:	68.1% 2,4-D acid equivalent
Batch/Lot No:	GHD-0832-46.
Description:	Dark brown liquid
Specific Gravity:	1.23 - 1.24

2. Test Animals

Species:	Rats
Strain:	Fischer 344
Sex:	Males and Females
Age:	6 weeks
Identification:	Ear tags.

3. Animal Husbandry

Housing:	1/cage.
Food:	Purina Certified Rodent Chow #5002 ad libitum
Water:	tap water ad libitum
Environment:	Temperature- 22 ± 2°C; Humidity- 40-60%

4. Treatment

Whole body exposures were conducted in 157 liter glass and stainless steel Rochester-type chambers under dynamic airflow conditions. The test aerosols were generated by pumping test material into a 1/4J spray nozzle where it was mixed with compressed air at 50 psi, and sprayed into the chamber. The particle size data were derived gravimetrically from aerosol samples collected at least once per exposure, in a six stage Marple cascade impactor.

Group of six rats/sex were exposed for a single-four hour duration to a stable aerosol concentration of the test material targeted at 5 mg/mL (limit dose).

5. Quality Assurance

A quality assurance statement was included in the report.

III. RESULTS

1. Chamber Atmosphere Conditions During Exposure

Time of Sample (min)	Concentration of Sample (mg/L)	Mean Temperature (°C)	Mean Chamber Airflow (l/min)
43	3.30	22.6 ± 0.5	30 ± 0.0
69	3.63		
114	3.53		
139	3.46		
175	3.43		
240	3.55		

Time-Weighted-Average (TWA) = 3.5 mg/L

Nominal Concentration = 12 mg/L

2. Particle Size

The mass median aerodynamic diameter (MMAD) of the aerosol was 2.1 μ, while the geometric standard deviation of the particle size distribution was 1.95.

3. Survival

All rats survived the exposure and appeared to be normal throughout the two-week observation period.

4. Clinical Observations

Rats appeared "wet" with test material immediately after exposure.

5. Body Weight

Following a slight weight loss one day post-exposure, animals gained weight during the observation period.

6. Necropsy

No treatment-related gross pathological changes were seen.

IV. CONCLUSION

The acute inhalation toxicity of DMA 6 Weed Killer, a herbicide formulation containing 68.1% of the dimethylamine salt of 2,4-dichlorophenoxyacetic acid, was evaluated in male and female Fischer 344 rats. The highest attainable time-weighted concentration (3.5 mg/L) produced no compound-related toxicity. The nominal concentration for the 3.5 mg/L exposure was 12 mg/L. The inhalation LD_{50} was > 3.5 mg/L.

TOXICITY CATEGORY: III

V. CORE CLASSIFICATION: Guideline; satisfies Guideline requirement [81-3] for an acute inhalation toxicity study.

PRIMARY REVIEWER: Jess Rowland, M.S, Toxicologist
Section II, Toxicology Branch II 01/07/92

SECONDARY REVIEWER: K. Clark Swentzel, Section Head
Section II, Toxicology Branch II

DATA EVALUATION REPORT

STUDY TYPE: Primary Eye Irritation **GUIDELINE: 81-4**

Caswell No. 315 O TRID No. 470165-041 HED PROJECT No. 1-2003

TEST MATERIAL: Dimethylamine salt of 2,4-Dichlorophenoxyacetic acid

SYNONYM: DMA 6 Weed Killer

REGISTRANT: Dow Chemical Co. Midland, MI

TESTING LABORATORY: Mammalian and Environmental Toxicology Research Laboratory, Dow Chemical Co.

STUDY IDENTIFICATION: None

TITLE OF REPORT: DMA 6: Primary Eye Irritation Study in New Zealand White Rabbits.

AUTHORS: R.E. Carreon and K.S. Rao

REPORT DATE: January 31, 1986

CONCLUSION: The eye irritation potential of DMA 6, a herbicide formulation containing 57.9% of dimethylamine salt of 2,4-dichlorophenoxyacetic acid, was evaluated in male and female New Zealand White rabbits. The test material was shown to be a severe eye irritant.

TOXICITY CATEGORY: I

CORE CLASSIFICATION: Guideline; satisfies Guideline requirement [81-4] for a primary eye irritation study.

I. INTRODUCTION

This Data Evaluation Report (DER) summarizes the experimental procedures and results of a primary eye irritation study of DMA 6 Weed Killer in rabbits.

II. MATERIALS AND METHODS

1. Test Material

Common Name:	DMA 6 Weed Killer
Active Ingredient:	**DMA salt of 2,4-D Acid**
Composition:	57.9% 2,4-D acid equivalent
Batch/Lot No.	GHD-0832-46.
Description:	Brown liquid
Flash Point:	TCC >195°F

2. Test Animals

Species: Rabbits
Strain: New Zealand White
Sex: Males and Females
Weight: 2.4 - 3 kg
Identification: Ear tags.

3. Animal Husbandry

Housing: 1/cage.
Food: Purina Certified Rodent Chow #5002 ad libitum
Water: tap water ad libitum
Environment: Temperature- 21°C; Humidity- 50%

4. Treatment

A dose of 0.1 mL was instilled into the conjunctival sac of the right eye of 5 female and 1 male rabbit. The left eye of all rabbits served as controls. Both eyes of all rabbits were examined at 1, 24, 48 and 72 hours post-instillation and again at 7, 14 and 21 days for conjunctival redness, chemosis, discharge, corneal opacity and reddening of the iris.

5. Quality Assurance

A quality assurance statement was included in the report.

III. RESULTS

The eyes of treated rabbits revealed moderate to marked conjunctival redness and chemosis, marked discharge, reddening of the iris, and slight to moderate corneal opacity. Signs of corneal irritation were still evident in all but one rabbit 21 days post-exposure. Irritation grades for individual animals are presented below:

Rabbit Eye Irritation Grades*

Observation Time	Animal Number	Redness	Conjunctivae Chemosis	Discharge	Corneal Opacity	Reddening of Iris
1 Hour	85A2784	2	3	3	1[b]	0
	85A2785	2	2	2	1[b]	1
	85A2786	2	2	3	1	1
	85A2787	2	3	3	1	0
	85A2788	2	3	1	1	0
	85A2789	2	2	3	1	0
24 Hours	85A2784	2	3	3	1	1
	85A2785	2	3	3	1	1
	85A2786	2	3	3	1	1
	85A2787	2	2	3	0	1
	85A2788	2	3	2	1	1
	85A2789	2	2	2	1	1
48 Hours	85A2784	2	4	3	2	1
	85A2785	2	4	3	2	1
	85A2786	2	3	3	1	1
	85A2787	2	2	3	0	1
	85A2788	2	4	3	1	1
	85A2789	2	3	3	1	1
72 Hours	85A2784	2	3	3	2	1
	85A2785	2	3	3	2	1
	85A2786	2	2	3	1	1
	85A2787	2	2	3	0	1
	85A2788	2	3	3	1	1
	85A2789	2	2	2	1	1
7 Days	85A2784	3	2	2	2	1
	85A2785	2	2	2	3	1
	85A2786	1	1	0	1	0
	85A2787	2	1	2	1	1
	85A2788	2	2	2	2	1
	85A2789	2	1	1	2	1
14 Days	85A2784	1	1	2	3[a]	1
	85A2785	1	1	2	3[a]	1
	85A2786	0	0	0	1[a]	0
	85A2787	1	0	1	1	0
	85A2788	2	1	2	4	1[a]
	85A2789	2	1	1	3[a]	1
21 Days	85A2784	1	1	1	3	A
	85A2785	1	1	1	2	0
	85A2786	0	0	0	0	0
	85A2787	0	0	0	2	0
	85A2788	1	1	0	4	A
	85A2789	2	1	1	A	A

*See Table :A for explanation of grades.
A = Cannot visualize due to opacity.
a Vascularization observed over the cornea.
b Surface of cornea appeared "dry".

IV. CONCLUSION: The eye irritation potential of DMA 6, a herbicide formulation containing 57.9% of dimethylamine salt of 2,4-dichlorophenoxyacetic acid, was evaluated in male and female New Zealand White rabbits. The test material was shown to be a severe eye irritant.

TOXICITY CATEGORY: I

V. CORE CLASSIFICATION: Guideline; satisfies Guideline requirement [81-4] for a primary eye irritation study.

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PRIMARY REVIEWER: Jess Rowland, M.S, Toxicologist
Section II, Toxicology Branch II

Jess Rowland 01/01/92

SECONDARY REVIEWER: K. Clark Swentzel, Section Head
Section II, Toxicology Branch II

DATA EVALUATION REPORT

STUDY TYPE: Primary Dermal Irritation **GUIDELINE: 81-5**

Caswell No. 315 O TRID No. 470165-042 HED PROJECT No. 1-2003

TEST MATERIAL: Dimethylamine salt of 2,4-Dichlorophenoxyacetic acid

SYNONYM: DMA 6 Weed Killer

REGISTRANT: Dow Chemical Co. Midland, MI

TESTING LABORATORY: Mammalian and Environmental Toxicology Research Laboratory, Dow Chemical Co.

STUDY IDENTIFICATION: None

TITLE OF REPORT: DMA 6 Weed Killer: Primary Dermal Irritation Study in New Zealand White Rabbits.

AUTHORS: M.M. Jeffrey and K.S. Rao

REPORT DATE: January 23, 1986

CONCLUSION: The dermal irritation potential of DMA 6 Weed Killer, a herbicide formulation containing 57.9% of dimethylamine salt of 2,4-dichlorophenoxyacetic acid, was evaluated in male and female New Zealand White rabbits. The test material was shown to be a non-irritant in the rabbit skin.

TOXICITY CATEGORY: IV

CORE CLASSIFICATION: Guideline; satisfies Guideline requirement [81-5] for a primary dermal irritation study.

I. INTRODUCTION

This Data Evaluation Report (DER) summarizes the experimental procedures and results of a primary dermal irritation study of DMA 6 Weed Killer in rabbits.

II. MATERIALS AND METHODS

1. Test Material

Common Name:	DMA 6 Weed Killer
Active Ingredient:	**DMA salt of 2,4-D Acid**
Composition:	57.9% 2,4-D acid equivalent
Batch/Lot No.	GHD-0832-46.
Description:	Brown liquid
Flash Point:	TCC >195°F
pH:	6.8 - 7.2

2. Test Animals

Species: Rabbits
Strain: New Zealand White
Sex: Males and Females
Weight: 2.7 - 2.9 kg
Identification: Ear tags.

3. Animal Husbandry

Housing: 1/cage.
Food: Purina Certified Rodent Chow #5002 ad libitum
Water: tap water ad libitum
Environment: Temperature- 21°C; Humidity- 50%

4. Treatment

A dose of 0.5 mL of undiluted test material was applied to the intact skin of shaved backs of four male and two female rabbits under a 4x4 cm 2-ply gauze patch that was held in place with adhesive tape. A flannel bandage was taped to the marginal hair of the rabbits. The gauze patches were removed after a four-hour exposure period. The application sites were examined and graded for erythema, edema, and necrosis within 30 minutes of patch removal and again at 24, 48 and 72 hours.

5. Quality Assurance

A quality assurance statement was included in the report.

III. RESULTS

The test material did not cause hyperemia or edema in any animals. Consequently the primary irritation score was 0. Thus, this material was not considered a primary irritant.

IV. CONCLUSION: The dermal irritation potential of DMA 6 Weed Killer, a herbicide formulation containing 57.9% of dimethylamine salt of 2,4-dichlorophenoxyacetic acid, was evaluated in male and female New Zealand White rabbits. The test material was shown to be a non-irritant in the rabbit skin.

TOXICITY CATEGORY: IV

V. CORE CLASSIFICATION: Guideline; satisfies Guideline requirement [81-5] for a primary dermal irritation study.

PRIMARY REVIEWER: Jess Rowland, M.S, Toxicologist
Section II, Toxicology Branch II

Jess Rowland 01/08/92

SECONDARY REVIEWER: K. Clark Swentzel, Section Head
Section II, Toxicology Branch II

DATA EVALUATION REPORT

STUDY TYPE: Dermal Sensitization **GUIDELINE:** 81-6

Caswell No. 315 O **TRID No. 470165-043** **HED PROJECT No. 1-2003**

TEST MATERIAL: Dimethylamine salt of 2,4-Dichlorophenoxyacetic acid

SYNONYM: DMA 6 Weed Killer

REGISTRANT: Dow Chemical Co. Midland, MI

TESTING LABORATORY: Mammalian and Environmental Toxicology Research Laboratory, Dow Chemical Co.

STUDY IDENTIFICATION: None

TITLE OF REPORT: DMA 6: Dermal Sensitization Potential in the Guinea pig.

AUTHORS: R.E. Carreon and K.S. Rao

REPORT DATE: November 12, 1985

CONCLUSION: The dermal sensitization potential of DMA 6 Weed Killer, a herbicide formulation containing dimethylamine salts of 2,4-dichlorophenoxyacetic acid (57.9%) was evaluated in male Hartley guinea pigs. The test material was not considered to be a dermal sensitizer.

CORE CLASSIFICATION: Guideline; satisfies Guideline requirement [81-6] for a dermal sensitization study.

I. INTRODUCTION

This Data Evaluation Report (DER) summarizes the experimental procedures and results of a dermal sensitization study of DMA 6 Weed Killer in guinea pigs.

II. MATERIALS AND METHODS

1. Test Material

Common Name:	DMA 6 Weed Killer
Active Ingredient:	**DMA salt of 2,4-D Acid**
Composition:	57.9% 2,4-D acid equivalent
Batch/Lot No.	GHD-0832-46.
Description:	Brown liquid
Flash Point:	TCC >195°F

2. Test Animals

Species: Guinea pigs
Strain: Hartley
Sex: Males
Weight: 251 - 307 g
Identification: Ear tags.

3. Animal Husbandry

Housing: 5/cage.
Food: Purina Certified Guinea Pig Chow #5026 ad libitum
Water: Tap water ad libitum
Environment: Temperature- 22°C; Humidity- 50%

4. Treatment (modified Maguire Method, 1973)

Following removal of hair from their backs, a group of 10 pigs received four applications of 0.1 mL of undiluted test material within 10 days during the insult phase of testing. An additional group of 10 pigs were treated with DER 331 epoxy resin (a known sensitizer) as a 10% solution in DOWANAOL DPM/Tween 80 (9:1). This group served as the positive controls. The materials were applied to an 15 x 15 mm gauze square patch, placed on the back of the pigs, covered first with MICROPORE and then secured with adhesive tape.

At the time of the third application, a total of 0.2 mL of Freund's Adjuvant was injected intradermally at multiple points adjacent to the insult site. Each time the insult patches were removed, observations for redness and/or edema were made and recorded. The animals were then allowed to rest for at least two weeks (induction period).

Following the resting period, both flanks of the animal were clipped and the left flank challenged with the undiluted test material. The challenge application was not covered. Skin response at these sites was recorded at 24 and 48 hours. Guinea pigs were weighed weekly throughout the study.

5. Quality Assurance

A quality assurance statement was included in the report.

III. RESULTS

The positive control (DER 331 epoxy resin) produced slight to marked redness in 10/10 guinea pigs. However, none of the 10 guinea pigs treated with the undiluted DMA 6 exhibited signs of any redness or edema.

IV. CONCLUSION: The dermal sensitization potential of DMA 6 Weed Killer, a herbicide formulation containing dimethylamine salts of 2,4-dichlorophenoxyacetic acid (57.9%) was evaluated in male Hartley guinea pigs. The test material was not considered to be a dermal sensitizer.

V. CORE CLASSIFICATION: Guideline; satisfies Guideline requirement [81-6] for a dermal sensitization study.

END